DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
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Bothell, WA 98021-4421

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9413832

October 23, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-05

Mr. Marvin D. Schmeichel, President
Fresh Juice Works, Incorporated
11431 Rainier Avenue South
Seattle, Washington 98178

WARNING LETTER

Dear Mr. Schmeichel:

On April 1, 3, and 23, 2003, the Food and Drug Administration (FDA) conducted an inspection of your juice processing firm located at 1431 Rainier Avenue South, Seattle, Washington. The inspection was conducted to determine your compliance with the FDA's juice processing regulation (21 CFR Part 120) and Good Manufacturing Practices (GMP) requirements for foods (21 CFR Part 110).

The juice processing regulation became effective on January 21, 2002. However, this regulation is not binding on small businesses as defined in 21 CFR 120.1(b)(1) until January 22, 2003, and is not binding on very small businesses as defined in 21 CFR 120.1(b)(2) until January 23, 2004. Your firm is a "small business" as defined in the juice processing regulation. The juice processing regulation requires that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to reduce or eliminate the likelihood that the identified hazards will occur. HACCP provides a systematic way of identifying, implementing, and documenting those measures that demonstrates to us, to your customers, and to consumers that you are routinely practicing food safety by design.

During our inspection, we determined that your firm produces the following 100% juice products: orange juice, lemon juice, lime juice, cider apple juice, and grapefruit juice. We understand that you have recently discontinued production of two other 100% juice products, carrot juice and cranberry apple juice. In several cases (orange juice, lime juice, and lemon juice), your firm uses more than one method to make the juice product. Juice products that are 100% juice are required to be produced consistent with the juice processing regulation, 21 CFR Part 120.

Our inspection identified several shortcomings in your production system that, upon preliminary review, appear to be deviations from the principles of HACCP and significant requirements of the program. Investigators Bennett-Hoffman, Capron, and Hicks provided you with a copy of the Inspectional Observations (Form FDA 483), which presents their evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

1. For each different process that you use to produce a particular 100% juice product, you must have a written hazard analysis, as required by 21 CFR 120.7. The hazard analysis for each 100% juice product process must determine whether there are any food safety hazards that are reasonably likely to occur during your production of that product using such process, and must identify control measures that you can apply to control those hazards. However, your firm has no written hazard analysis for any of the 100% juice products that you produce.

2. For each different process that you use to produce a particular 100% juice product, you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur during such production, as required by 21 CFR 120.8(a). This HACCP plan must be based on the written hazard analysis required by 21 CFR 120.7. However, your firm does not have a HACCP plan to control the food safety hazard of pathogens for any of the processes used to make 100% juice products.

3. In relation to plant sanitation controls, you must monitor conditions and practices during processing with sufficient frequency to ensure conformance with current GMP regulations, as required by 21 CFR 120.6(b). However, our inspection showed that your firm does not monitor, with sufficient frequency, prevention of cross-contamination; maintenance of hand-washing facilities; protection of food, food packaging materials, and food contact surfaces from chemical, physical, and biological hazards; and exclusion of pests from the plant. These failures are evidenced by the following observations:

    a. A production employee entered the building from outside, held his hands under running water, wiped them on his pants, put on latex gloves, and then began to handle raw fruit, which he was zesting. (Zested fruit is used in some of the 100% juice products that you produce.) This employee did not wash or sanitize his hands prior to touching the raw fruit.

    b. Production utensils were hung on nails mounted in an unfinished wooden wall post in the processing area.

    c. Cartons of raw materials and finished products were stored directly on the floor inside the coolers and freezer.

    d. A production employee had chewing tobacco in his mouth while he manufactured Cider Raspberry Apple Juice.

e. The hand-wash sink in the process area was not stocked with soap and paper towels.

f. In the storage room adjacent to the processing area, uncapped plastic bottles were stored beneath a shelf of maintenance tools and chemicals. The bottles were partially covered with soiled cardboard.

g. Uncapped plastic bottle stock, in an open plastic bag, was stored on the floor, adjacent to a box of lacquer thinner, spackle, paint, and painting implements.

h. A live fly entered the processing area through the front entrance, which was left open by a production employee.

4. You must maintain sanitation standard operating procedure implementation records that document monitoring and corrections, as required by 21 CFR 120.6(c) and 21 CFR 120.12(a)(1). However, your firm does not maintain sanitation standard operating procedure implementation records for 1) safety of the water that comes into contact with food or food contact surfaces; 2) condition and cleanliness of food contact surfaces; 3) prevention of cross contamination from insanitary objects; 4) maintenance of hand washing, hand sanitizing, and toilet facilities; 5) protection of food, food packaging, and food contact surfaces from adulteration; 6) proper labeling, storage, and use of toxic compounds; 7) control of employee health conditions that could result in contamination; and 8) exclusion of pests from the food plant.

Juices that are required to be produced under a HACCP system complying with 21 CFR Part 120, but are not so produced are considered adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) under the provisions of 21 CFR 120.9. Adulterated foods are subject to seizure, condemnation, and forfeiture (section 304 of the Act), and those responsible for causing such adulteration may be enjoined (section 302 of the Act) or prosecuted (section 303 of the Act.)

During the inspection our investigators also collected labels and made observations regarding the labeling for a number of different juice products. According to that information, you receive several single strength juice products in unopened in bulk containers that have been previously pasteurized by another processor. You blend fresh-squeezed, unpasteurized juice and/or remnants of zested citrus fruits with this previously pasteurized juice and repackage it. The labels on the products that you repackage declare the product to be pasteurized. The products (Just Squeezed 100% Orange Juice, Just Squeezed Pure Orange Juice, Just Squeezed Pure Lemonade Juice, Just Squeezed Strawberry Lemonade, Just Squeezed Pure Grapefruit Juice, Just Squeezed Pure Lemon Juice, Just Squeezed Pure Lime Juice, Just Pressed Cider Pure Raspberry Apple Juice, Just Pressed Pure Blackberry Apple Juice, Just Pressed Pure Cranberry Apple Juice, and Just Pressed Pure Strawberry Apple Juice) are misbranded within the meaning of section 403(a)(1) of the Act in that the products purport to be pasteurized when, in fact, the final products have not been pasteurized.

The above violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject food to legal action. It is your responsibility to ensure that all of your products are in compliance with applicable statutes and regulations enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Mr. Donovan at (425) 483-4906.

Sincerely,

Charles M. Breen
District Director

cc: WSDA with disclosure statement